



REMARKS

Claims 1-31 are pending in this Application. Claims 1-6 and 14-31 have been withdrawn from consideration. Applicants submit herewith cancellation of claim 9 and amendments of claims 7 and 10-12.

Claim 7 is amended to clarify that the method is for the treatment of sexual dysfunction. The claim is also amended to incorporate the limitations of claim 9 that the subject have a sexual dysfunction. The amendments are fully supported in the specification, for example, at page 6, lines 1-6, at page 9, lines 30-34 and at claim 9. Claims 10-12 are amended to correct the antecedent basis and claim numbers from which they depend as a result of the cancellation of claim 9. Claim 13 is amended to correct antecedent basis with respect to admixing with a pharmaceutically acceptable carrier, diluent or excipient. Hence, Applicants submit that no new matter has been added by these amendments.

Applicants' cancellation of claim 9 is intended without waiver or prejudice. Applicants reserve the right to present the cancelled claim or deleted subject matter in one or more divisional applications.

Objections in the Specification

The Examiner has objected to the title of the invention as not being descriptive. Applicants have amended the title as suggested by the Examiner.

The Examiner has objected to the text at page 40, line 26 and page 74, line 6 as containing embedded hyperlink and/or other browser-executable code. Applicants have amended the specification to delete the objected to text.

The Examiner has noted the failure to use the proper form of the trademark designation for LIPITOR®. Applicants have corrected the designation.

The Examiner has noted that the drawings at pages 86-90 are not preceded with the title "BRIEF DESCRIPTION OF THE FIGURES". Applicants have added the title.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected claims 7-13 under 35 U.S.C. §112, first paragraph as not reasonably providing enablement for the general "treatment" of a subject. The Examiner has noted that the specification is enabling for the treatment of sexual dysfunction.

Accordingly, Applicants have amended claim 7 by clarifying that the claim is directed to methods of treatment of sexual dysfunction. Claims 8 and 10-13 are each dependent from claim 7 and, as such, are enabled together with claim 7 in light of the present amendment.

Based upon the amendment of claim 7, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §102; Further Rejection Based on Inherency

The Examiner has rejected claims 7 and 8 under 35 U.S.C. §102(b) as being anticipated by Foulkes et al.. The Examiner notes that Foulkes et al. teaches the use of one of the compounds disclosed by Applicants, albeit, not for the treatment of sexual dysfunction, but for growth of a human being. The Examiner further states that although Foulkes et al. do not expressly disclose that the compound is capable of modulating an IK_{Ca} channel activity in the sexual genitalia of a subject and capable of mediating a relaxation in the corpus cavernosal smooth muscle tone, such would have been inherent in the disclosed method.

The Examiner points to the recitation in claim 7 of a method of treatment without expressly identifying the therapeutic indication as the basis for the claim reading on the administration of an agent capable of modulating an IK_{Ca} channel for any therapeutic purpose.

Applicants have amended claim 7 to methods of treatment of sexual dysfunction which involve administering a selective IK_{Ca} channel modulator to a subject having a sexual dysfunction. These amendments incorporate the limitations of claim 9 which are, as noted by the Examiner's rejection of only claims 7 and 8, not anticipated by Foulkes et al. As the Examiner will clearly discern, Foulkes et al. does not disclose methods of

treatment of sexual dysfunction by administering a selective IK_{Ca} channel modulator to a subject having a sexual dysfunction.

Based upon the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Rejections Under 35 U.S.C. §103

The Examiner has rejected claims 7-13 under 35 U.S.C. §103(a) as being obvious over Simonsen et al. in view of Pedersen et al., Stedman's Medical Dictionary and Fritz et al.

The Examiner bases the rejection on speculative language in Simonsen et al. about the possible use of agonists of calcium-activated potassium channels in the treatment of impotence.

As stated by the U.S. Court of Appeals for the Federal Circuit, "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art. Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). The Examiner has the burden of establishing a case of prima facie obviousness. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Applicants respectfully submit that the Examiner has failed to meet the burden of showing prima facie obviousness, in that, the references cited by the Examiner fail to suggest to one of ordinary skill in the art that Applicants' methods of treatment of sexual dysfunction using a selective modulator of the IK_{Ca} channel should be carried out or that carrying out such methods would reasonably likely be met with success.

In citing Simonsen et al., the Examiner notes that the reference is silent as to a particular type of agonist of calcium-activated potassium channels that may be employed in the treatment of impotence. Applicants agree that such a description is missing. However, Applicants submit that a much more critical piece of information is missing.

There is nothing in Simonsen et al. or any of the other references cited by the Examiner that in any way suggest or provide guidance for selecting the IK_{Ca} channel over any of the other known calcium-activated potassium channels in the treatment of sexual dysfunction. There are at least four known calcium-activated potassium channels. *See, for example, Trend in Pharmacological Sciences (TIPS)*, 12th Ed. 2001 Nomenclature Supplement, page 119 (submitted herewith). Each of these channels is uniquely different, having its own structure and physical properties. As would be evident to one with skill in the art, agents that modulate one channel do not necessarily modulate another. This can be seen in the TIPS reference with respect to the four describe calcium-activated potassium channels.

Not only do the references cited by the Examiner fail to suggest or provide guidance for selecting the IK_{Ca} channel over any of the other known calcium-activated potassium channels, but, in fact, the relevant art teaches away from Applicants' invention. For example, Christ, G.J. (2002) *J. Andrology*, 23, S10-S19 (submitted herewith) advocates focusing on two other potassium channels, the metabolically regulated K_{ATP} channel and the large conductance calcium-activated maxi-K channel (at pp. S13-S14).

Hence, Applicants submit that the Examiner has failed to reach its burden, as set forth by the U.S. Court of Appeals for the Federal Circuit, of showing a suggestion in the prior art that Applicants invention should be carried out and would have a reasonable likelihood of success.

Based upon the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

Rejections for Obviousness-Type Double Patenting

The Examiner has provisionally rejected claims 7-13 under the judicially created doctrine of obviousness-type double patenting over claim 34 of co-pending U.S. Patent Application No. 10/017,273.

Applicants present herewith a Terminal Disclaimer of Pfizer Inc., the common assignee of both the instant Application and U.S. Patent Application No. 10/017,273.

Based upon the foregoing, Applicants respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

In view of the foregoing, Applicants respectfully request reconsideration of the Office Action mailed April 27, 2005 and that a timely Notice of Allowance be issued in this Application.

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Respectfully submitted,



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